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B. Shone

ATTENTION: BOX AFTER FINAL  
RESPONSE UNDER 37 C.F.R. § 1.116  
EXPEDITED PROCEDURE REQUESTED  
EXAMINING GROUP 1600  
PATENT

Attorney Docket No. 2405.0167

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: )

Mads Liendgaard Vigh et al. )

Serial No.: 09/255,655 )

Group Art Unit: 1623

Filed: February 23, 1999 )

Examiner: H. Owens, Jr.

For: USE OF D-TAGATOSE AS A  
PREBIOTIC FOOD  
COMPONENT )

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Assistant Commissioner for Patents  
Washington, DC 20231

Sir:

**SUPPLEMENTAL REPLY UNDER 37 C.F.R. § 1.116**

This is a reply to the Advisory Action of September 19, 2000, and the telephone conference with Supervisory Examiner Gary Geist regarding the content of that Advisory Action.

As presently understood, the Office is relying on a principle of inherency to satisfy its burden of establishing a *prima facie* case of obviousness. Although this principle has not been articulated as supporting the position of the Examiner in any Office action to date, it is now understood, particularly from the telephone conference with Mr. Geist, to be the basis for establishing that the prior art relied on (i.e., Zehner in view of Morelli et al., MacFarlane et al. and Mortensen et al.) suggests administering

D-tagatose to a human to selectively induce production of butyrate and selectively stimulate growth of Lactobacilli and lactic acid bacteria.

The Examiner's apparent reliance on the principle of inherency in this application is not a sufficient basis for establishing a *prima facie* case of obviousness. As established in a long line of cases, "... the inherency of an advantage and its obviousness are entirely different questions. That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown." In *re* Shetty, 195 U.S.P.Q. 753, 757 (CCPA 1977) - a copy is attached for the convenience of the Examiner.

During the course of prosecution, as pointed out in the personal interview conducted on July 13, 2000, and as recited in all claims remaining in the application, the prior art does not teach or suggest that the administration of D-tagatose can be or should be administered in an amount to "selectively" induce the production of butyrate (claim 1 and claims dependent thereon) and "selectively" stimulate the growth of Lactobacilli and lactic acid bacteria in the human colon (claim 7 and claims dependent thereon). There is nothing in the prior art relied on by the Examiner that shows or even suggests that a person of ordinary skill in the art would recognize or appreciate that D-tagatose will "selectively" induce butyrate production and "selectively" stimulate growth of Lactobacilli and lactic acid bacteria in the human colon. As noted by the Court in reversing an obviousness rejection in *In re Naylor*, 152 U.S.P.Q. 106, 108 (CCPA 1966), "... inherency is quite immaterial if, as the record establishes here, one of ordinary skill in the art would not appreciate or recognize that inherent result."

Zehner teaches that some fermentation of D-tagatose by Lactobacilli has been observed (col. 2, lines 56-57), but that D-tagatose is either not metabolized by the body or is metabolized to such a small extent, it will have little or no effect upon normal body functions (col. 1, lines 63-66). This is not a teaching or suggestion to administer an amount of D-tagatose effective to "selectively" induce the production of butyrate or "selectively" stimulate the growth of Lactobacilli and lactic acid bacteria in the human colon as recited in the claimed invention. The references relied on by the Examiner fail to appreciate or recognize the results recited in these claims or the amount of D-tagatose effective to produce those results. Zehner does not suggest any particular amount of D-tagatose to be administered, so it is not clear whether the recited results of the claimed processes would be inherent. Even assuming, *arguendo*, they were inherent, this is not sufficient to render the claimed invention *prima facie* obvious. Prior to the present disclosure, the prior art did not suggest a use, much less an effective amount, for "selectively" inducing the production of butyrate or "selectively" stimulating the growth of Lactobacilli and lactic acid bacteria in the human colon.

Prompt and favorable reconsideration of this application is respectfully requested.

Please grant any extensions of time required to enter this reply and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: December 27, 2000

By: Charles E. Van Horn  
Charles E. Van Horn  
Reg. No. 40,266

Attachment: In re Shetty case